

## Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

### Skin Health Institute

<b>Title</b>	Skin Health Institute Skin Cancer Database
<b>Protocol Number</b>	1
<b>Coordinating Principal Investigator/ Principal Investigator</b>	Associate Professor Alvin Chong
<b>Associate Investigator(s)</b>	Dr Blake Mumford, Dr Jane Li
<b>Location</b>	Skin Health Institute

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## Part 1 What does my participation involve?

### 1 Introduction

You are invited to take part in this research project, Skin Health Institute Skin Cancer Database. This is because you attend an outpatient clinic at the Skin Health Institute. The research project is aiming to collect information about people who are immunosuppressed, have received an organ transplant, and people who are at high risk of developing skin cancer for other reasons.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you wish to participate in the research project, you will be asked to sign the consent section. By signing you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

### 2 What is the purpose of this research?

The purpose of this research project is to establish a database which will be used to investigate the trends in skin diseases that develop in people who have compromised immune systems and normal immune systems. It aims to determine the frequency and type of skin diseases in people who attend our clinics, how they were diagnosed and treated, and what factors may have contributed to their development. The findings from this research project may improve the care these patients receive in the future.

This research project has been initiated by Associate Professor Alvin Chong, the head of the Skin Health Institute Transplant Dermatology.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project and you will not be paid for your participation.

### **3 What does participation in this research involve?**

All patients who attend the Skin Health Institute outpatient clinics are eligible to participate in the study. No information will be collected until you have signed this consent form.

If you consent to participating in this study, we will collect information about you in a database each time you attend the clinic. This information will only be obtained from the electronic medical record that we use to deliver your usual care. Information that will be collected includes:

- Personal information, such as your name, date of birth, and sex
- Contact information, such as your email address
- Health information, such as your medical history, family history, any skin diseases you are diagnosed with and the treatment for these
- The results of any tests that are performed as part of your usual care
- Your current medications

This is an ongoing research project with no fixed end date.

### **4 What do I have to do?**

If you agree to participate in the study, you will not be required to do anything:

- You will **not** be exposed to any experimental tests, procedures, or treatment.
- You will **not** need to complete any additional questionnaires.
- You will **not** be required to attend any additional appointments.

### **5 Other relevant information about the research project**

This study will be carried out at the Skin Health Institute, Carlton, Australia. Only researchers employed by the Skin Health Institute will be involved in data collection.

We may involve researchers at other organisations when we analyse the data. For example, if we require the services of a biostatistician. We may also disclose basic identifying information to other organisations for the purpose of obtaining additional information about you from other clinical databases. The information that will be disclosed is limited to your name, date of birth, and address. This disclosure will only occur with approval from a Human Research Ethics Committee.

This research project will be monitored by the Principal Investigator, Associate Professor Alvin Chong, and the St Vincent's Hospital Melbourne Human Research Ethics Committee.

### **6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this consent form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will **not** affect your routine treatment, your relationship with those treating you, or your relationship with the Skin Health Institute.

### **7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at the Skin Health Institute. If you do not wish to have your information included in the Skin Health Institute Skin Cancer Database, your information will be recorded only in your electronic medical record.

### **8 What are the possible benefits of taking part?**

The Skin Health Institute Skin Cancer Database will be used to further medical knowledge and improve the care of immunosuppressed patients and patients at high risk of skin cancers. There may be no direct benefit to you from your participation in this research.

### **9 What are the possible risks and disadvantages of taking part?**

While this research does not involve any interventional treatment, there are some risks pertaining to data security. Potential risks relating to data security include:

- Malicious or inadvertent release or publication of your information
- Malicious use of your information for the purposes of blackmail or identity theft
- Emotional distress arising as a result of the above

Every effort will be made to ensure that your information is stored securely. The Skin Health Institute has a dedicated Information Technology department that are responsible for ensuring security is maintained to the highest standard.

During the collection of your information, if we become aware of an error relating to the care that you have received, we will notify your treating doctor who will address the issue.

### **10 Can I have other treatments during this research project?**

Yes. Your participation in this research project will not influence the treatment(s) you receive in any way.

### **11 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team.

If you do withdraw your consent during the research project, the study doctor will not collect additional personal information from you. Personal information already collected may need to be retained to ensure that the results of the research project can be measured properly, and that we comply with the requirements of relevant medical journal(s). You should be aware that data collected up to the time you withdraw will form part of the research project results.

### **12 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include:

- A decision by the principal investigator to cease the research project.
- Loss of funding provided by the Skin Health Institute.

### **13 What happens when the research project ends?**

If a decision is made to cease the research project, all your personal information will be securely deleted.

When findings from the research project are published in a medical journal, we will notify you via email and publish the findings on our website and social media accounts. These publications occur periodically.

## **Part 2 How is the research project being conducted?**

### **14 What will happen to information about me?**

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Your information will be stored in an identifiable format in a database located at the Skin Health Institute. Your information will be accessible only to members of the research team who are listed in this consent form. Your information will only be used for the purpose of this research project.

Basic identifying information may be disclosed to other organisation(s) where we require additional information about you from another database. Should this occur only your name, date of birth, and address will be disclosed to the third-party organisation. This disclosure will only occur after approval has been granted by a Human Research Ethics Committee.

Information about you will be obtained from your health records held at the Skin Health Institute for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

The purpose of this database is to monitor people over a long period of time to identify trends in skin disease. It may be used to produce multiple medical publications over several years. As such, your information will be kept indefinitely.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Results from this research project will only be published in aggregate and will not include information which could identify you.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## **15 Complaints and compensation**

If you have a complaint regarding your participation in this research project, you can contact any member of the research team listed at the end of this consent form. Alternatively, you can contact the Skin Health Institute Customer Services Manager Ms Julianna Hays on +61 3 9639 3575.

## **16 Who is organising and funding the research?**

This research project is being conducted by Associate Professor Alvin Chong.

The Skin Health Institute may benefit financially from this research project if, for example, the project assists the Skin Health Institute to obtain approval for a new treatment.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the Skin Health Institute, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

## **17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital Melbourne.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

This research project has also been approved by the Skin Health Institute.

## **18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project, you can contact the principal study doctor on +61 3 9623 9400 or any of the following people:

### **Clinical contact person**

Name	Blake Mumford
Position	Dermatology Research Fellow/Study Coordinator
Telephone	+61 3 9623 9400

Email	b.mumford@skinhealthinstitute.org.au
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For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

Name	Julianna Hays
Position	Customer Services Manager
Telephone	+61 3 9639 3575
Email	jhays@skinhealthinstitute.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	St Vincent's Hospital Melbourne Human Research Ethics Committee
HREC Executive Officer	HREC Executive Officer
Telephone	+61 3 9231 1954
Email	research.ethics@svhm.org.au

# Consent Form - *Adult providing own consent*

**Title** Skin Health Institute Skin Cancer Database  
**Protocol Number** 1  
**Coordinating Principal Investigator/  
Principal Investigator** Associate Professor Alvin Chong  
**Associate Investigator(s)** Dr Blake Mumford, Dr Jane Li  
**Location** Skin Health Institute, Carlton, Victoria, Australia

## **Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Skin Health Institute concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Name of Participant (please print) _____
Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____
Signature _____ Date _____

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

## **Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____
Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature